Dkt. 58332/JPW/EMW/APE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ni

Nicole Suciu-Foca

Serial No.:

09/333,809

Examiner: Not Yet Known

Filed

June 15, 1999

For

GENERATION OF ANTIGEN SPECIFIC T SUPPRESSOR CELLS

FOR TREATMENT OF REJECTION

1185 Avenue of the Americas New York, New York 10036

August 9, 1999

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Applicant submits herewith an Information Disclosure Statement under 37 C.F.R. §1.56.

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures:

- 1. Banchereau, J., Steinman, R. M. (1998) "Dendritic cells and the control of immunity," Nature 392:245-252. (Exhibit 1).
- 2. Barker, T. D., Weissman, D., Daucher, J. A., Roche, K. M., and Fauci, A. S. (1996) "Identification of multiple and distinct CD8+ T cell supressor activities: dichotomy between infected and unifected individuals, evolution with progression of disease and sensitivity to gamma radiation," Clin. Immunol. 156:4476-4483. (Exhibit 3).
- 3. Bennett, S. R. M., Carbone, F. R., Karamalis, F., Flavell, R. A., Miller, J., and Heath, W. R. (1998) "Help for cytotoxic-T-cell responses is mediated by CD40 signaling,"

 Nature 393:478-480. (Exhibit 2).
- 4. Ciubotariu, R., Colovai, A. I., Pennesi, G., Liu, Z., Smith,

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- D., Berlocco, P., Cortesini, R., Suciu-Foca, N. (1998) "Specific supression of human CD4+ Th cell responses to pig MHC antigens by CD8+CD28- regulatory T cells," J. Immuno. 161(10): 5193-5202. (Exhibit 4).
- 5. Damle, N. K., Mohagheghpour, N., Hansen, J. A., and Engleman, E. G. (1993) "Alloantigen-specific cytotoxic and suppressor T lymphocytes are derived from phenotypically distinct precursors," J. Immunol. 131:2296-2300. (Exhibit 5).
- 6. Groux, H., O'Garra, A., Bigler, M., Rouleau, M., Antonenko, S., de Vires, J. E., and Roncarolo, M. G. (1997) "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis," Nature 389:737-742. (Exhibit 6).
- 7. Jiang, S., Tugulea, S., Pennesi, G., Liu, Z., Mulder, A., Lederman, S., Harris, P., Cortesini, R. and Suciu-Foca, N. (1998) "Induction of MHC-class I restricted human supressor T cells by peptide priming in vitro. Hum. Immunol. 59:690-699. (Exhibit 7).
- 8. Lanier, L. L., O'Fallon, S., Somoza, C., Philips, J. H., Linsey, P. S., Okumura, K., Ito, D. and Azuma, M. (1995) "CD80 (B7) and CD86 (B70) provide similar costimulatory signals for T cell proliferation, cytokine production and generation of CTL," J. Immunol. 154:97-105. (Exhibit 8).
- 9. Liu, Z., Tugulea, S., Cortesini, R., Suciu-Foca, N. (1998)
 "Specific suppression of T helper alloreactivity by alloMHC class I-restricted CD8+CD28- T cells," Int. Immunol.
 10(6):775-783. (Exhibit 9).
- 10. Lombardi, G., Sidhu, S., Batchelor, R., Lechler, R. (1994)
 "Anergic T cells as supressor cells in vitro," Science

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264:1587-1589. (Exhibit 10).

- 11. Noble, A., Zhao, Z., and Cantor, H. (1998) "Supression of immune responses by CD8 cells. II. Qa-1 on activated B cells stimulates CD8 cell supression of T Helper 2 responses," J. Immunol. 160:566-571. (Exhibit 11).
- 12. Qin, S., Cobbold, S. P., Pope, H., Elliott, J., Kioussis,
 D., Davies, J., and Waldmann, H. (1993) "'Infectious'
 transplantation tolerance," Science 259:974-977. (Exhibit 12).
- 13. Ridge, J. P., Di Rosa, F., and Matzinger, P. (1998) "A conditioned dendritic cell can be a temporal bridge between a CD4+ T-Helper and a T-Killer cell," *Nature* 393:474-478. (Exhibit 13).
- 14. Schoenberger, S. P., Toes, R. E. M., Van Der Voort, E. I. H., Offringa, R., and Melief, C. J. M., (1998) "T-Cell help for cytotoxic T lymphocytes is mediated by CD40-CD40L interactions," Nature 393:480-483. (Exhibit 14).
- 15. Schwartz, R. H. (1992) "Costimulation of T lymphocytes: The role of CD28, CTLA-4, and B7/BB1 in interleuken-2 production and immunotherapy," Cell 71:1065-1068. (Exhibit 15).
- 16. Tan, P., Anasetti, C., Hansen, J. A., Melrose, J., Brunvand, M., Bradshaw, J., Ledbetter, J. A., and Linsey, P. S. (1993) "Induction of alloantigen-specific hyporesponsiveness in human T lymphocytes by blocking interaction of CD28 with its natural ligand B7/BB1," J. Exp. Med. 177:165-173. (Exhibit 16).
- 17. Yang, Y., Wilson, J. M. (1996) "CD40 ligand-dependent T

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cell activation: Requirement of B7-CD28 signaling through CD40," Science 273:1862-1864. (Exhibit 17).

Each of the above-listed references is listed again on the accompanying PTO Form 1449 (Exhibit A), and copies of references 1-17 are attached hereto as Exhibits 1-17, respectively.

Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents,

Assistant Commissioner for Patents, Washington, D.C. 20231.

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John P. White

Reg. No. 28,678

Date

John (P. \White

Registration No. 28,678 Attorney for the Applicant

Cooper & Dunham LLP

1185 Avenue of the Americas New York, New York 10036

(212) 278-0400



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Group Art Unit Unknown

U.S. PATENT DOCUMENTS Date Class Examiner Document Number Name Subclass Filing Date Initial if Appropriate FOREIGN PATENT DOCUMENTS Translation **Document Number** Date Country Class Subclass Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Banchereau J, Steinman, R. M., (1998) "Dendritic cells and the control of immunity," Nature 392:245-252. (Exhibit 1). Bennett, S. R. M., Carbone, F. R., Karamalis, F., Flavell, R. A., Miller, J., and Heath, W R (1998) "Help for cytotoxic-T-cell responses is mediated by CD40 signaling," Nature 393:478-480. (Exhibit 2). **EXAMINER** DATE CONSIDERED *EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in

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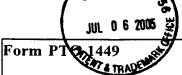
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Applicant

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